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510(k) SUMMARY

Pall Medical's Laparoshield Conditioned Insufflation Set

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Pall Medical
2200 Northern Boulevard
East Hills, NY 11548-1209

Phone: (516) 484-5400
Facsimile: (516) 484-3672

Contact Person: Leonard S. Berman, PhD

Date Prepared: December 23, 2003

Name of Device and Name/Address of Sponsor

Laparoshield Conditioned Insufflation Set

Pall Medical
2200 Northern Boulevard
East Hills, NY 11548-1209

Common or Usual Name

Laparoscopic Insufflator

Classification Name

Laparoscopic Insufflator

Predicate Devices

Laparoshield Conditioned Insufflation Set

Intended Use / Indications for Use

The modified Laparoshield Conditioned Insufflation Set ("Laparoshield") is intended to be used as an accessory to an insufflator to heat, humidify and filter a gas stream used for insufflation during laparoscopic surgery. It is indicated for use with CO_2.

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Technological Characteristics

The modified Laparoshield consists of a length of silicon coated heating wire coiled in the insufflation tubing. Heating control is performed by a constant voltage/voltage limited power supply. The patient end of the heater wire is encased in a hydrating wick. Gas flows through the annulus created by the wick and outer tubing. The proximity of the heating wire and hydrated wick produce warms and humidifies CO_2 from the insufflator. A temperature strip indicates under, normal, and over temperature conditions. The set has a universal connector for compatibility with insufflation machines with Luer, 15mm/22mm ISO 5356-1 and hose-barb gas ports and a trocar.

Performance Data

Testing was performed to evaluate the temperature and humidity output at two different per minute average CO_2 flow rates. In all instances, the modified Laparoshield met its performance specifications.

Substantial Equivalence

The modified Laparoshield and the cleared Laparoshield have the same intended use, which is as an accessory to an insufflator to heat, humidify and filter a gas stream used for insufflation during laparoscopic surgery. The devices are identical except for their heating control features and a material in two components. These minor technological differences do not present new issues of safety or effectiveness. Moreover, bench tests show that the modified Laparoshield is as safe and effective as the cleared Laparoshield, which has the same performance specifications. Thus, the modified Laparoshield is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2004

Pall Medical
% Mr. Jonathan S. Kahan
Regulatory Counsel
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K033991
Trade/Device Name: Laparoshield Conditioned Insufflation Set
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: 85 HIF
Dated: December 23, 2003
Received: December 23, 2003

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K033991

Device Name: Laparoshield Conditioned Insufflation Set

Indications for Use:

The Laparoshield Conditioned Insufflation Set is intended for use as an accessory to an insufflator to heat, humidify, and filter a gas stream used for insufflation during laparoscopic surgery. The device is indicated for use with CO_2.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

David A. Segovia

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033991